



U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2

October 15, 2018

BY ELECTRONIC MAIL

Robert Law, Ph.D.
de maximis, inc.
186 Center Street, Suite 290
Clinton, New Jersey 08809

Re: Fall 2009 Sediment Toxicity Test Data for the Lower Passaic River Study Area, dated
November 20, 2015

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) has reviewed the revised *Fall 2009 Sediment Toxicity Test Data for the Lower Passaic River Study Area*, dated November 20, 2015. The report was prepared by Windward Environmental LLC on behalf of the Cooperating Parties Group (CPG) for the Lower Passaic River Study Area.

EPA approves the responses to comments received on September 24, 2012 and the revised report dated November 20, 2015. Please address the minor comments listed below and finalize the report in accordance with Section X, Paragraph 44(a) of the Agreement.

Sincerely,

A handwritten signature in black ink, appearing to read "Diane Salkie".

Diane Salkie, Remedial Project Manager
Lower Passaic River Study Area RI/FS

Cc: Zizila, F. (EPA)
Sivak, M. (EPA)
Hyatt, B. (CPG)
Otto, W. (CPG)

Response to USEPA Comments Received September 24, 2012 to the Draft Fall 2009 Sediment Toxicity Test Data for the LPRSA, dated January 31, 2012

No.	Section	EPA's General Comment	CPG's Response	EPA's Response
1	General Comment	<p>In the report, numbers and percent of samples with control-adjusted response rates of greater than 75% are reported. While not stated explicitly, it appears that such statements are intended to indicate that samples with such results are not toxic to the endpoint measured. As procedures for designating sediment samples as toxic and not toxic have not been determined for the BERA, it is premature and inappropriate to include any presumptive toxicity designations in the report. Statements on numbers/percent of samples with control-adjusted response rates of greater than 75% should be removed.</p> <p>Ultimately, the data should be evaluated using multiple methods, such as direct comparison with the controls, comparison with other reference locations or reference data sets, and lines of evidence using the sediment concentrations and community surveys.</p>	<p>The text has been revised to remove statements discussing the numbers/percent of samples with control-adjusted response rates greater than 75%.</p>	Addressed
2	General Comment	<p>Throughout the report, the results presented are normalized based on the laboratory control that was run for each batch of tests. Normalizing test results to the laboratory control is not appropriate. In general, when results are control corrected, the data may actually “double-dip”. In other words, instead of just comparing site sample survival to laboratory control survival, when you have already adjusted for control mortality, you introduce the potential to hide samples that showed toxic effects. The purpose of the laboratory control is to evaluate the health of each batch of organisms run concurrently with each test in order to prevent false positive results (i.e., test indicates toxicity when in fact mortality is due to poor organism health). Not to artificially inflate survival and growth results. For example, mean organism survival in the 28-day freshwater <i>H. azteca</i> test ranged from 13.8% to 88.8%. When normalized to the laboratory control, mean survival ranged from 16.2% to 104.4%. The latter is not representative of true test results, and it is impossible to have a test resulting in survival over 100%.</p> <p>Since a site reference has yet to be agreed upon, it is appropriate to statistically compare site samples to the laboratory control, but not to adjust the results. Since the report (including the figures) present only normalized results, the document is misleading. It is recommended that the entire document be revised with results presented “as is” along with a statistical comparison to the laboratory control and not normalized.</p>	<p>The CPG takes exception to the tone and insinuations in the Region’s comment. There was no attempt to “double-dip”, hide toxic effects or “artificially inflate survival and growth rates”.</p> <p>For the purposes of the 2009 toxicity test data report, the presentation of results has been revised and is presented as mean results for each of the samples rather than as control-normalized results.</p> <p>This issue was discussed with USEPA on January 9, 2014. Please note that control-normalized toxicity data is typically done in environmental assessments. This is a QC step to account for batch control. NOAA and EPA’s REMAP data are presented this way.</p>	Addressed
3	General Comment	<p>For the midge analyses: The biomass/growth calculations that appear to be anomalous are likely due to pupation/emergence of test organisms that were excluded from the mean growth and biomass calculations. The large number of replicates with at least one organism emerging/pupating is troublesome. However, the overall impact on the data should be minimal. It does not affect the survival or weight determination, but does impact the biomass interpretation. As such, the actual survival including pupa and emerged individuals should be used, and the value of 10 for midges should always be used, even if more were removed for the biomass.</p>	<p>Comment noted. For the purposes of the 2009 toxicity test data report, Chironomus biomass results have been presented using both the start count of 10 and also the start count adjusted for the number of organisms that either pupated or emerged during the test. For example, if 8 organisms survived at the end of the exposure but 2 of those survivors had pupated during the test, the weight of the pan was divided by 8 rather than 10 so that the overall biomass wasn’t reduced due to the fast maturation of 2 of the larvae. Biomass is intended to be a combined survival/mortality endpoint.</p>	<p>Response is acceptable.</p> <p>Note: in the response to comment 3rd sentence, “For example, if 8 organisms survived at the end of the exposure but 2 of those survivors had pupated during the test, the weight of the pan was divided by 8 rather than 10.”</p> <p>Should read: “For example, if 10 organisms survived at the end of the exposure but 2...”</p>

Response to USEPA Comments Received September 24, 2012 to the Draft Fall 2009 Sediment Toxicity Test Data for the LPRSA, dated January 31, 2012

No.	Section	EPA's General Comment	CPG's Response	EPA's Response
4	General Comment	For the Hyalella analyses: There were a number of replicates (10) with more than 10 organisms per beaker, but the calculations of mean growth and biomass assumed 10/beaker. Please recalculate mean biomass based on the actual number of amphipods at the beginning of the test, and adjust total biomass to 10 individuals to be consistent with the other data. Tests with more than 12 per beaker should be dropped as a replicate as they were likely double stocked.	Calculations for mean weight and biomass had been adjusted for the 10 replicates with more than 10 organisms per beaker at the end of the test. See the start count in the replicate data sheet in Appendix B. For replicates with 12 or 11 at the end of the test (7 replicates), the start count was adjusted to either 12 or 11. For the 3 replicates with more than 12, the start count was adjusted to 20 assuming that the beaker had been double loaded. For 2 replicates in the same test with zero organisms at the end of the test but good survival in other replicates for the same sample, it was assumed that no organisms were added to the test chambers and the mean survival and growth calculations excluded those two replicates.	Addressed
5	General Comment	Statistical comparisons: Note that NOAA ran statistics to compare with the CPG results, and found some differences. They intend to repeat their statistical analysis for growth & biomass with the final midge and Hyalella results, and the data may need to be flagged, adjusted, and/or a memo to file created.	Comment noted. Statistical comparisons were conducted by EnviroSystems using the statistical software package CETIS that is designed for analysis of toxicity tests, including sediment tests. We can discuss differences in the analyses conducted by NOAA.	Addressed
6	Page 1, First paragraph, third sentence	This sentence is awkward as it seems to imply that the SQT approach is only being used to support a risk assessment of benthic invertebrate communities. Recommend revising the sentence to say that it is being used to support the "baseline ecological risk assessment which will included assessment endpoints aimed specifically at protecting benthic invertebrate communities" or something similar.	The sentence has been revised as suggested.	Addressed
7	Page 4, Second paragraph, second sentence	Please identify the location that was dropped.	LPRT16F was the location that was dropped. This information has been added to the text.	Addressed
8	Page 8, Third paragraph	Please identify the five locations that were not sampled using the power grab sampler.	Sediment at the following 5 stations had sample collected for toxicity testing using methods other than the power grab sampler: LPRT04F, LPRT10D, LPRT09G, LPRT17A, and LPRT17D This information has been added to the text.	Addressed
9	Page 11, First paragraph, last sentence	The text states that freshwater samples were tested in five batches; however, review of Tables B-1 through B-3 in Appendix B indicate that there were six freshwater batches. Please clarify, and revise as appropriate.	Freshwater sediment samples were tested in 5 batches as stated in the text. A total of 7 batches were run; 2 estuarine (Batches 2 and 7) and 5 freshwater (Batches 1, 3, 4, 5, and 6).	Addressed

Response to USEPA Comments Received September 24, 2012 to the Draft Fall 2009 Sediment Toxicity Test Data for the LPRSA, dated January 31, 2012

No.	Section	EPA's General Comment	CPG's Response	EPA's Response
10	Section 2.3.3, Pages 15 to 17	For ampelisca, it appears that the ASTM protocol was not followed. Daily renewal was used, when the protocol states no renewal. Using a renewal test instead of a static test may shift the toxicity curve, but the data should still be useable and comparable to the control. However, the potential shift in the toxicity curve should be discussed in the uncertainty section.	The laboratory SOP describing daily test solution renewal was reviewed and approved by USEPA Region 2 in advance of testing and attached to the Benthic QAPP. It is the CPG's understanding that the Region's Partner Agencies participated in the review of the Benthic QAPP and associated SOPs including the <i>Ampelisca</i> SOP prior to the Region's approval; therefore, it is unclear why the Region and its Partner Agencies would assert that the approved method was not used. Moreover, it is the CPG's understanding that the Region's split samples were run using the same protocol using renewal. The potential shift in the toxicity curve will be discussed in the uncertainty section of the BERA.	Addressed
11	Page 19, Third paragraph, second sentence	The sentence states that <i>H. azteca</i> used in estuarine samples were "acclimated to, and cultured in 10-ppt seawater". <i>Hyalella</i> are cultured in freshwater and, if needed, acclimated to the appropriate salinity. Please delete "cultured in" from the sentence.	The phrase "cultured in" has been deleted from the sentence.	Addressed
12	Page 20, Table 3-1	Results should be presented as percent survival, not how they relate to negative control data. Presenting data in this form can be misleading. It is suggested that columns be titled in a way that best presents the results. For example, one column may be titled "90% to 100% survival" 80%-90% survival" etc. and the corresponding rows would include the number of samples characterized by organism survival within that range. Estuarine survival of <i>Ampelisca</i> is reported as 20 and 4 at the >75% and >50% to <75% categories, respectively. Based on a review of Table B-3 Sediment toxicity Test Results as Percent of Control, the reported values should be 21 and 3 for these categories. Please confirm the results reported and revise, as necessary.	To avoid any misinterpretation, Table 3-1 has been deleted and replaced with 3 tables, one for each species. The results are presented as a mean of the replicates for each sample and are not control-normalized. .	Addressed
13	Page 25, First paragraph, second sentence	The phrase "and minimum" is mentioned in sequence twice. Please revise.	The text has been revised.	Addressed
14	Page 36, First paragraph	Not all of the data was deemed usable by the data validator. Please revise the first sentence to read "Results of the validation determined that most data generated by the sediment testing program are of good quality and usable for any purpose."	The word "most" has been added to the sentence.	Addressed
15	Page 37, Second bullet	The text notes that the incorrect numbers of organisms were placed in test chambers during one of the <i>H. azteca</i> and <i>C. dilutus</i> tests, but seems to downplay these issues. Some of the language as noted in the data validation report (Appendix D) regarding uncertainties, use of caution, and recalculations should be included in this bullet to further inform the reader.	Text has been added to provide a stronger emphasis on the uncertainty associated with the incorrect number of organism added to a small percentage of the test chambers in the <i>Hyalella</i> and <i>Chironomus</i> tests.	Addressed
16	Page 37, Section 4.2, first sentence	Please revise the reference to read "(EPA 1998)".	The citation has been updated to include the author.	Addressed
17	Page 38, Section 4.3	Please delete the last sentence of this section, and remove the word "urban" from the remaining language. Alternatively, delete the entire section, as it is not necessary.	The section on influence of habitat characteristics on toxicity has been deleted from the data report.	Addressed

Response to USEPA Comments Received September 24, 2012 to the Draft Fall 2009 Sediment Toxicity Test Data for the LPRSA, dated January 31, 2012

No.	Section	EPA's General Comment	CPG's Response	EPA's Response
18	Page 38, Section 5	This section should summarize the results for each individual test. The purpose of the control is to evaluate the health of each batch of organisms run concurrently with each test in order to prevent false positive results (i.e., test indicates toxicity when in fact mortality is due to poor organism health). Since no site reference was available, it is appropriate to statistically compare test results to the laboratory control, but this was not done in the document. Instead, controls were used to normalize test results, and to present the data in terms of percent control survival or growth which is not appropriate. See General Comment 2.	The presentation of results has been revised to summarize results for each individual test by batch. A statistical comparison to control data is not presented in the report. Interpretative analyses will be reserved for the BERA.	Addressed
19	Page 39, Last bullet	Please delete the last bullet.	The bullet has been deleted.	Addressed
20	Appendix D, Page 9, Section 3 Batch 1 summary	The first sentence states "Batch 1 sediment tests were completed with no protocol deviations and no water quality deviations." The paragraph then goes on to identify a protocol deviation regarding the temperature logger not being started until day 6. This surely constitutes a protocol deviation. The validation report needs to be revised to capture this incident in Section 10, Final QA determination.	The validation report has been revised as suggested.	Addressed Edit has been made to the text in the main report but Appendix D remains unchanged.
21	Appendix D, Last paragraph prior to the Reference section	The following statement was included in the data validation report by the third party validator: However, I note that ESI's SOPs and the Quality Assurance Project Plan's "Quality indicators for toxicity tests based on ASTM and USEPA protocols" (Table 11-2) (Windward Environmental 2009) contains a number of test criteria that contain "must" statements, including temperature averages and ranges for most of the tests. On the basis of these "must" statements, many of the tests would be considered failures due to temperature deviations alone. While I do not think that the temperature deviations were serious enough to fail these tests, I defer to the regulatory agencies for final decisions regarding stringent application of these "must" criteria." It is agreed that minor deviations in temperature and others factors most likely did not significantly impact test results, but this statement should remain in the report.	Comment noted. The language in the report that summarizes validation has been updated accordingly.	Addressed
22 New Comment	Page 21, Table			Table number is inaccurate. It should be changed to "Table 3-2". Needs to be revised in Table of Contents also.